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#16

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Charles W. Ashbrook
Assistant General Counsel, Pharmaceutical Patents
WARNER-LAMBERT COMPANY
Parke-Davis Pharmaceutical Research Division
2800 Plymouth Road
Ann Arbor MI 48105

In Re: Patent Term Extension
Application for
U.S. Patent No. 4,559,334

NOTICE OF FINAL DETERMINATION

A determination has been made that U.S. Patent No. 4,559,334, which claims the human drug product OMNICEF TABLETS® (cefdinir), is eligible for patent term extension under 35 U.S.C. § 156. The period of extension has been determined to be 1,601 days, as correctly stated in the application for patent term extension.

A single request for reconsideration of this final determination as to the length of extension of the term of the patent may be made if filed within one month of the date of this notice. Extensions of time under 37 CFR § 1.136(a) are not applicable to this time period. In the absence of such request for reconsideration, the Commissioner will issue a certificate of extension, under seal, for a period of 1,601 days.

The period of extension has been calculated using the FDA determination of the length of the regulatory review period published in the Federal Register of May 20, 1999 (64 Fed. Reg. 27578).[1] Under 35 U.S.C. § 156(c):

Period of Extension = ½ (Testing Phase) + Approval Phase
= ½ (2,288) + 457
= 1,601 days

Since the regulatory review period began June 1, 1990, after the patent issue date (December 17, 1985), the entire period has been considered in the above determination. No determination of a lack of due diligence under 35 U.S.C. § 156(c)(1) was made.

Neither the limitations of 35 U.S.C. § 156(g)(6) nor the 14 year limitation of 35 U.S.C. § 156(c)(3) operate to reduce the period of extension determined above.

Upon issuance of the certificate of extension, the following information will be published in the Official Gazette:

U.S. Patent No.	:	4,559,334
Granted	:	December 17, 1985
Original Expiration Date	:	December 17, 2002
Applicant	:	Takao Takaya et al.

[1]The regulatory review period for Omnicef Oral Suspension published in the Federal Register on May 20, 1999 (64 Fed. Reg. 27579) is a different regulatory review period.

Owner of Record	:	Fujisawa Pharmaceutical Co., Ltd
Title	:	7-Substituted-3-Vinyl-3-Cephem Compounds and Processes for Production of the Same
Classification	:	514/202
Product Trade Name	:	OMNICEF TABLETS® (cefdinir)
Term Extended	:	1,601 days
Expiration Date of Extension	:	May 6, 2007

Any correspondence with respect to this matter should be addressed as follows:

By mail: Assistant Commissioner for Patents
Box Patent Ext.
Washington, D.C. 20231

By FAX: (703) 308-6916 or (703)872-9411
Attn: Special Program Law Office

By hand: Crystal Plaza Four, Suite 3C23
2201 South Clark Place
Arlington, VA 22202

Telephone inquiries related to this determination should be directed to the undersigned at (703) 306-3159.

Karin Tyson
Senior Legal Advisor
Special Program Law Office
Office of the Deputy Assistant Commissioner
for Patent Policy and Projects

cc: David T. Read
Acting Director Regulatory Policy Staff, CDER
Food and Drug Administration
1451 Rockville Pike, HFD-7
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RE: OMNICEF TABLETS® (cefdinir)
FDA Docket No.: 98E-0754